



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|---------------------|
| 10/538,343 | 06/10/2005 | Keith Gibson | 10383.204-US | 5444 |
| 25908 | 7590 | 05/19/2006 | EXAMINER | |
| NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110 | | | | RAGHU, GANAPATHIRAM |
| ART UNIT | | PAPER NUMBER | | |
| | | 1652 | | |

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/538,343 | GIBSON ET AL. |
| | Examiner | Art Unit |
| | Ganapathirama Raghu | 1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 06/10/2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-6 and 22-27 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-6 and 22-27 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>06/10/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-6 and 22-27 are pending in this application for examination and are now under consideration.

Priority

Acknowledgment is made of applicants claim for priority under 35 U.S.C. 119(a)-(d). This application is a 371 of PCT/DK03/00844 and claims the priority date of 12/10/2003 and Denmark Application, 2002 01898 filed on 12/11/2002.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 06/10/ 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the Examiner is considering the information disclosure statement.

Objection: Specification

The use of trademarks through out the specification (for example, pages 40-51) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 5 recites the broad recitation pH range of 4-11, and the claim also recites preferably pH 5.5-10.5 which is the narrower statement of the range/limitation.

Claim 6 recites a broad limitation, genus "*Thielavia*" together with a narrow limitation preferably "*Thielavia terrestris*" and especially "*Thielavia terrestris* NRRL 8126".

Claim 23 recites the broad period of time between 2 minutes and 24 hours, and the claim also recites preferably 10 minutes to 60 minutes.

Claim 26 recites the broad period of time between 1 minute and 1 hour, and the claim also recites preferably 5 minutes to 30 minutes. Correction is required.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the phrase “derived from the genus *Thielavia*”. It is not clear to the examiner as to what the phrase “derived from the genus *Thielavia*” means in the context of the above claim, is this synonymous with “obtained from *Thielavia*” or does it include mutants thereof. Clarification is required.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the phrase “sequence shown in SEQ ID NO: 4”. It is not clear to the examiner as to what the phrase “shown in” means in the context of the above claim. It is not clear whether the isolated polypeptide indeed actually has the sequence SEQ ID NO: 4 or whether SEQ ID NO: 4 is a representative sequence of the isolated polypeptide. Examiner suggests applicants to make a direct reference to the SEQ ID NO: such as “the polypeptide sequence of SEQ ID NO: 4”. Clarification is required.

Claims 24 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 24 and 27 recite the phrase “total enzyme protein”. It is not clear to the examiner as to what the phrase “total enzyme protein” means in the context of the above claim, is this the weight of total protein or only the weight of all enzymes? if the latter is contemplated in the claims, how is this determined?, Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 is directed to a detergent composition comprising an endo-glucanase, wherein the endoglucanase is an anti-redeposition endo-glucanase. Claim 3 is directed to a detergent composition comprising anionic tensides and a combination of endo-glucanase and a fungal cellulase. Claims 2 and 3 are rejected under this section 35 U.S.C. 112, because the claims are directed to a genus of polypeptides with no support in the specification for the structural details associated with the function i.e., endo-glucanase or cellulase activity. No description of identifying characteristics or functional characterization recognizing all of the sequences i.e., 1) polypeptides having endo-glucanase activity from all or any source and 2) polypeptides having cellulase activity from any or all fungal sources has been provided in the specification. No information, beyond the characterization of the polypeptide with SEQ ID NO: 2 or a polypeptide having an amino acid of 1-773 amino acid residues of SEQ ID NO: 2 and having endo-glucanase activity or a fungal cellulase having the amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4 has been provided by the applicants, which would indicate that they had possession of the claimed genus of the polypeptides having 1) having endo-glucanase activity from any or all sources and 2) polypeptides having cellulase activity from any fungal source. The

Art Unit: 1652

specification does not contain any disclosure of the sequence and structure of all the polypeptides within the scope of the claimed genus. The disclosed information is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus of polypeptides. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-6 and 22-27 depending therefrom are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a detergent composition comprising an endo-glucanase with anti-redeposition property, comprising a polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 and optionally a fungal cellulase having the amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4, does not reasonably provide enablement for a detergent composition comprising any polypeptide with anti-redeposition property or any endo-glucanase, having 90% sequence identity to a polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 or a fragment thereof and having endo-glucanase activity and in addition said detergent composition comprising any polypeptide having at least 70% sequence identity to a polypeptide having an amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4 or a fragment thereof and having cellulase activity. The specification does not enable any person skilled in the art to which

it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with the claim.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-6 and 22-27 are so broad as to encompass any detergent composition comprising polypeptides, having 90% sequence identity to a polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 or a fragment thereof and having endo-glucanase activity with anti-redeposition property and in addition said detergent composition comprising a polypeptides having at least 70% sequence identity to a polypeptide having an amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4 or a fragment thereof and having cellulase activity, while claim 2 even more broadly encompasses any endo-glucanase having anti-redeposition activity. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires knowledge and guidance with regard to which amino acids in the protein's sequence and the respective codons in its polynucleotide, if any, are tolerant of modification and which are

conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the encoded proteins' structure relates to its function. However, in this case the disclosure is limited to the polypeptide sequence of only one endo-glucanase i.e., SEQ ID NO: 2 or polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 and the polypeptide sequence of only one cellulase i.e., SEQ ID NO: 4 or a polypeptide having an amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4. It would require undue experimentation of the skilled artisan to make and use the claimed polypeptides. The specification is limited to teaching the use of the endo-glucanase, comprising a polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 and the cellulase, comprising a polypeptide having an amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4, but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claims, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claim, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in

Art Unit: 1652

obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions or deletions.

The specification does not support the broad scope of the claims which encompass any detergent composition comprising polypeptide, having 90% sequence identity to a polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 or a fragment thereof and having endo-glucanase activity with anti-redeposition property and in addition said detergent composition comprising a polypeptide having at least 70% sequence identity to a polypeptide having an amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4 or a fragment thereof and having cellulase activity, because the specification does not establish: (A) regions of the protein/polynucleotide structure which may be modified without affecting the activity of encoded endo-glucanase or cellulase; (B) the general tolerance of the polypeptide and the polynucleotide encoding endo-glucanase or cellulase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue or the respective codon in the polynucleotide with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claim broadly including detergents comprising polypeptides with an enormous number of modifications. The scope of the claim must bear a reasonable correlation with the scope of

enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of endoglucanases with anti-redeposition property and cellulases having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5 and 22-23 are rejected under 35 U.S.C. 102 (e) as being anticipated by Outtrup et al., (USPGPUB: 2005/0215450 A1, publication date of 09/29/2005, which is a DIV of application No.: 10/479446 filed on 12/02/2003 claiming the priority of PCT/DK02/00381 filed on 06/06/2002 and further claiming the priority of provisional application No.: 60/302446 filed on 06/29/2001). Claims 1, 2, 5 and 22-23 are directed to a detergent composition comprising an endo-glucanase, said endo-glucanase is a antiredeposition endo-glucanase, comprising an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 or 90% sequence identity to a polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 or a fragment thereof and having endo-glucanase activity, wherein said endo-glucanase is active at

least in the pH range of 4-11, preferably pH of 5.5-10.5. Outtrup et al., disclose an isolated polynucleotide (SEQ ID NO: 1) sequence that encodes a polypeptide (SEQ ID NO: 2) that is 100% identical to SEQ ID NO: 2 of the instant application and exhibits endo-glucanase activity, said endo-glucanase is a antiredeposition endo-glucanase (page 14, paragraph 0023) with a pH optima of 6-10.5 (page 2, paragraph 0019) and use of the enzyme as a detergent composition (page 1, Background section). Therefore, Outtrup et al., anticipate claims 1, 2, 5 and 22-23 as written (see copy of the sequence alignments provided).

Claim Rejections: 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Outtrup et al., (USPGPUB: 2005/0215450 A1, publication date of 09/29/2005, which is a DIV of application No.: 10/479446 filed on 12/02/2003 claiming the priority of PCT/DK02/00381 filed on 06/06/2002 and further claiming the priority of provisional application No.: 60/302446 filed on 06/29/2001) as applied to claims 1, 2, 5 and 22-23 above and further in view of Hakamada et al., (Biosci. Biotechnol. Biochem., 2000, Vol. 64 (11): 2281-2289) Lund et al., (US Patent No.: 5958082, date of patent 09/28/1999), Schulein et al., (US Patent No.: 6001639, date of patent 12/14/1999) and Clarkson et al., (US Patent No.: 5290474, date of patent 03/01/1994).

As discussed above (see 102 (e) rejection) Outtrup et al., al., teach the physico-chemical properties and the use of an endo-glucanase with anti-redeposition property as a detergent composition in textile applications. However said reference is silent on the use of additional fungal cellulase, a polypeptide having at least 70% sequence identity to a polypeptide having an amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4 or a fragment thereof and having cellulase activity (as it applies to claims 3, 4and 6) and a process of washing fabric wherein the weight ratio of endo-glucanase protein component to the total enzyme protein is less than 1:2.

Hakamada et al., (*supra*) disclose the purification, kinetic profiles, thermostability and biophysical characterization of an alkaline endo-glucanase (Abstract section, page 2281) having 98.3% sequence homology to SEQ ID NO: 2 of the instant application (see sequence alignment provided). The said enzyme is suitable for use as an effective detergent additive (Introduction section, page 2281) and has pH optima of about 9.0 in 0.1 M glycine-NaOH buffer (Results and Discussion section, third paragraph, page 2286).

Lund et al., and Schulein et al., (*supra*) disclose detergent composition with anionic tensides (page 35, paragraph 3 of Schulein et al.,) and comprising a polypeptide having a cellulase activity from *Thielavia terrestris* NRRL 8126 (Lund et al., claims 1 and 7; same source as the instant application) with 100% homology to SEQ ID NO: 4 of the instant application (see copy of the sequence alignments provided).

Clarkson et al., (*supra*) disclose the detergent compositions consisting of endo-glucanase and cellulase plus other enzymes like exo-cellulobiohydrolase, β -glucosidase and a method for washing fabrics with said detergent composition, wherein the weight ratio of said endo-glucanase protein component to the total enzyme protein ranges from 20%-50% i.e., 1:5-1:2 (Column 4, Detailed description of the invention) and claim 1, wherein endo-glucanase protein component to the total enzyme protein is 40% i. e., 1: 2.5 (column 24).

One of ordinary skill in the art would be motivated to make a detergent composition comprising endo-glucanase with anti-redeposition property (as taught by Outtrup et al., or Hakamada et al.,) and cellulase (as taught by Lund et al., Schulein et al., and Clarkson et al.,), as the above cited references teach the properties of the enzymes and their use as fabric and textile detergents and other related applications including the appropriate weight ratio of the endo-glucanase component to the total enzyme protein in the detergent composition. One of ordinary skill in the art would have a reasonable expectation of success, because of the clear establishment of the properties and the role of the enzymes, endo-glucanase and cellulase in the combined teachings for the production and use of a detergent composition.

Therefore, the above references render claims 1-6 and 22-27 *prima facie* obvious to one of ordinary skill in the art.

Conclusion

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652
May 04, 2006.

Rebecca E. Prouty
REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1600